K091309

6 510(K) SUMMARY AS REQUIRED BY 21 CFR 807.92

510(k) Number Not yet assigned

Date Prepared May 1, 2009

NOV - 5 2009

Submitter Information

DGIMed Ortho, Inc.
12400 Whitewater Drive, Suite 2010
Minnetonka, MN 55343

Contact Person:

Scott P. Youngstrom
VP, Finance & COO
phone: (651) 442-6990

Device Information

Trade Name:	Revolution Femoral Intramedullary Nail System
Common Name:	Intramedullary Fixation Rod and Accessories
Classification:	Class II
Product Code:	HSB
Regulation:	21 CFR 888.3020
Panel:	87 – Orthopedic

Predicate Devices

Device	Manufacturer	510(k) Status
Russell-Taylor Femoral Nail	Smith & Nephew	K893377
Cannulated Retrograde/Antegrade Femoral Nail EXPERT System	Synthes	K033618
T2 Femoral Nailing System	Stryker Corp.	K912930

6.1 Device Description

The Revolution Femoral Intramedullary Nail System permits an antegrade intramedullary approach for fixation of fractures of the femur. The Revolution Femoral Intramedullary Nail is a closed section, cannulated, thick walled, mirror finished, curved intramedullary fixation device containing two proximal and two distal holes to accept locking screws which thread transversely though the proximal and distal third of the femur. The Nail is available in a variety of diameters and lengths.

Locking screws are also included as a component of the Nail system. The locking screws are designed to reduce the likelihood of shortening and rotation of femoral fractures. The locking screws are available in a single diameter and a variety of lengths.

The ancillary instrumentation include standard orthopedic instruments for accessing the femoral medullary canal, preparing the bone for placement and installation of the intramedullary nail and locking screws, and removal of the intramedullary nail and screws, if required..

6.2 Intended Use

The Revolution Femoral Intramedullary Nail System is indicated for use in orthopedic intramedullary nailing procedures: midline femoral fractures, femoral fractures in multiple trauma patients, fractures in the morbidly obese patient, fractures in osteoporotic bone or malunions and nonunions.

6.3 Summary of Non-clinical Testing

The safety and performance of the Revolution Femoral Intramedullary Nail System have been substantiated through non-clinical testing. Results of testing confirm that the Revolution Femoral Intramedullary Nail System reliably performs as intended. No new questions of safety or effectiveness have been raised.

6.4 Substantial Equivalence

The Revolution Femoral Intramedullary Nail System's product information, technological comparison to predicate products, and test results demonstrate that the Revolution Femoral Intramedullary Nail System is safe and performs as intended. Any differences in technological features raise no new questions of safety or effectiveness. Revolution Femoral Intramedullary Nail System is substantially equivalent to the currently marketed predicate devices with respect to intended use, materials and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DGIMed Ortho, Inc.
% Mr. Scott Youngstrom
12400 Whitewater Drive, Suite 2010
Minnetonka, MN 55343

NOV - 5 2009

Re: K091309
Trade/Device Name: Revolution Femoral Intramedullary Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: September 25, 2009
Received: September 28, 2009

Dear Mr. Youngstrom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's

(CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): not yet assigned

Device Name: Revolution Femoral Intramedullary Nail System

Indications for Use:

The Revolution Femoral Intramedullary Nail System is indicated for use in orthopaedic intramedullary nailing procedures: midline femoral fractures, femoral fractures in multiple trauma patients, fractures in the morbidly obese patient, fractures in osteoporotic bone or malunions and nonunions.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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